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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,596	08/17/2005	Masayuki Ii	084437-0184	1802

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EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,596	Il ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 of PCT/JP03/04396 filed on 04/07/2003.

Claims 1-20 are pending.

Lack of Unity

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-6, drawn to an agent comprising cycloalkene compound or a compound represented by formula (I) or formula (II), and a method of treatment of severe sepsis comprising administering an effective amount of compound represented by formula (I) or formula (II).

Group II, claims 7-14, 16, 18-19 drawn to a TLR signal inhibitor comprising non-peptide compound or a compound represented by formula (I) or formula (II), and a method for the inhibition of TLR signal comprising administering an effective amount of a non-peptide compound.

Group III, claims 15, 17 drawn to a method for the treatment of a disease caused by a change in TLR signal, which comprises administration of an effective amount of a non-peptide compound.

Group IV, claim 20, drawn to a method for the treatment of severe sepsis or organ dysfunction, which comprises inhibition of TLR signal.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the invention of Group I is drawn to an agent comprising cycloalkene compound or a compound represented by formula (I) or formula (II), and a method of treatment of severe sepsis comprising administering the same agent. The invention of Group II is drawn to a TLR signal inhibitor comprising non-peptide compound or a compound represented by formula (I) or formula (II), and a method for the inhibition of TLR signal comprising administering the non-peptide compound. The invention of Group III is drawn to a method for the treatment of a disease caused by a change in TLR signal, which comprises administration of an effective amount of a non-peptide compound. The invention of Group IV, is drawn to a method for the treatment of severe sepsis or organ dysfunction, which comprises inhibition of TLR signal.

The inventions of Groups I to IV are separate and distinct each from the other, since given the fact that the method of treatments in these groups are well known to have different modes of operation, different functions, and different effects. Therefore, each group above has different modes of operation and different functions from each other.

Because each of the method of use herein relate to a separate field of medical technology, a single general inventive concept is not seen to be present. The search and examination of all inventions would place an undue burden on the office in view of

the diversity of the therapeutic methods and the corresponding diversity in the field of search for each.

According to 37 CFR 1.475, if an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present

According to 37 CFR 1.475 (d), if multiple products, processes of manufacture or uses are claimed, the first invention of each mentioned in the claims of the application and the first recited invention of each of the other catogeries related thereto will be considered as the main invention in the claims. See PCT Article 17(3)(a) and paragraph 1.476(c).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one or more claim remaining in the application. Any amendment of inventorship must be accompanied by request under 37 CFR 1.48(b) and by fee required under 37 CFR 1.17(i).

Species Election

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1) a plurality of disclosed patentably distinct non-peptide compounds of formula (I) or formula (II).

2) a plurality of disclosed patentably distinct drugs as in claim 4

If applicant elects group I, applicant is further required to elect a single disclosed non-peptide compound of formula (I) or formula (II), and a drug as in claim 4.

If applicant elects group II-III, applicant is further required to elect a single disclosed non-peptide compound of formula (I) or formula (II).

Currently, claims 1-19 are generic to a plurality of disclosed patentably distinct compounds of formula (I) or formula (II). Given the fact that chemical compounds that are not similar in structure have different physical, chemical, biological and physiological properties or activities, the instant compounds of formula (I) or formula (II) will have different chemical, biological and physiological properties, and different effects. For example in formula (I), compounds wherein R^o is H will have different properties from compounds wherein R^o and R in combination form a bond.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

A telephone call to the applicant's agent to request an oral election was not made, due to the complexity of the restriction.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached Monday-Friday on 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni
Patent Examiner
Art Unit 1617
/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617